

PTO/SB/08A (07-05)

Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

|       |   |    |   |                        |                 |
|-------|---|----|---|------------------------|-----------------|
| Sheet | 1 | of | 6 | Attorney Docket Number | 021819-000130US |
|-------|---|----|---|------------------------|-----------------|

**Complete if Known**

|                      |                          |
|----------------------|--------------------------|
| Application Number   | 10/780,114               |
| Filing Date          | February 17, 2004        |
| First Named Inventor | Dow, Steve W.            |
| Art Unit             | 1633                     |
| Examiner Name        | Anne Marie Sabrina Wehbe |

**U.S. PATENT DOCUMENTS**

| Examiner<br>Initials* | Cite<br>No. | Document Number                          | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
|-----------------------|-------------|--|--------------------------------|--|---|
|                       |             | Number Kind Code <sup>2</sup> (if known) |                                |  |   |
| AW                    | AA          | US-4,957,735                             | 09/18/1990                     | Huang  |   |
|                       | AB          | US-5,013,556                             | 05/07/1991                     | Woodie, et al.                                     |   |
|                       | AC          | US-5,043,164                             | 08/27/1991                     | Huang, et al.                                      |   |
|                       | AD          | US-5,399,346                             | 03/21/1995                     | Anderson, et al.                                   |   |
|                       | AE          | US-5,580,859                             | 12/03/1996                     | Felgner, et al.                                    |   |
|                       | AF          | US-5,589,466                             | 12/31/1996                     | Felgner, et al.                                    |   |
|                       | AG          | US-5,593,972                             | 01/41/1997                     | Weiner, et al.                                     |   |
|                       | AH          | US-5,641,662                             | 06/24/1997                     | Debs, et al.                                       |   |
|                       | AI          | US-5,643,578                             | 07/01/1997                     | Robinson, et al.                                   |   |
|                       | AJ          | US-5,663,153                             | 09/02/1997                     | Hutcherson, et al.                                 |   |
|                       | AK          | US-5,676,954                             | 10/14/1997                     | Brigham  |   |
|                       | AL          | US-5,679,647                             | 10/21/1997                     | Carson, et al.                                     |   |
|                       | AM          | US-5,686,101                             | 11/11/1997                     | Tagawa, et al.                                     |   |
|                       | AN          | US-5,693,622                             | 12/02/1997                     | Wolff, et al.                                      |   |
|                       | AO          | US-5,703,055                             | 12/30/1997                     | Felgner, et al.                                    |   |
|                       | AP          | US-5,703,057                             | 12/30/1997                     | Johnston et al.                                    |   |
|                       | AQ          | US-5,705,187                             | 01/06/1998                     | Unger  |   |
|                       | AR          | US-5,705,385                             | 01/06/1998                     | Bally, et al.                                      |   |
|                       | AS          | US-5,723,335                             | 03/03/1998                     | Hutcherson, et al.                                 |   |
|                       | AT          | US-5,817,856                             | 10/06/1998                     | Tirosh, et al.                                     |   |
|                       | AU          | US-5,820,873                             | 10/13/1998                     | Choi, et al.                                       |   |
|                       | AV          | US-5,827,703                             | 10/27/1998                     | Debs, et al.                                       |   |
|                       | AW          | US-5,830,878                             | 11/03/1998                     | Gorman, et al.                                     |   |
|                       | AX          | US-5,976,567                             | 11/02/1999                     | Wheeler, et al.                                    |   |
|                       | AY          | US-5,981,501                             | 11/09/1999                     | Wheeler, et al.                                    |   |
|                       | AZ          | US-6,121,247                             | 09/19/2000                     | Huang, et al.                                      |   |
|                       | BA          | US-6,194,388 B1                          | 02/27/2001                     | Krieg, et al.                                      |   |
|                       | BB          | US-6,207,646 B1                          | 03/27/2001                     | Krieg, et al.                                      |   |
|                       | BC          | US-6,224,901 B1                          | 05/01/2001                     | Li, et al.   |   |
|                       | BD          | US-6,239,116 B1                          | 05/29/2001                     | Krieg, et al.                                      |   |
|                       | BE          | US-6,287,591 B1                          | 09/11/2001                     | Semple, et al.                                     |   |
|                       | BF          | US-6,339,068 B1                          | 01/15/2002                     | Krieg, et al.                                      |   |
|                       | BG          | US-6,406,705 B1                          | 06/18/2002                     | Davis, et al.                                      |   |
|                       | BH          | US-6,534,484 B1                          | 03/18/2003                     | Wheeler, et al.                                    |   |
|                       | BI          | US-6,589,940                             | 07/2003                        | Raz, et al.  |   |

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| Examiner<br>Signature | Date<br>Considered |
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Kind Codes of U.S. Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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|   |                          |    | First Named Inventor     | Dow, Steve W.     |  |
|   |                          |    | Art Unit                 | 1633              |  |
| Examiner Name   | Anne Marie Sabrina Wehbe |    |                          |                   |  |
| Attorney Docket Number  | 021819-000130US          |    |                          |                   |  |
| Sheet   | 2                        | of | 6                        |                   |  |

| U.S. PATENT DOCUMENTS |                       |   |                                |  |   |
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| Examiner Initials*    | Cite No. <sup>1</sup> | Document Number<br>Number Kind Code <sup>2</sup> (if known) | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
| AW<br>↓               | BJ                    | US-6,627,615 B1   | 09/30/2003                     | Debs, et al.                                       |   |
|                       | BK                    | US-US2002/0110586 A1  | 08/15/2002                     | Madden, et al.                                     |   |
|                       | BL                    | US-US2002/0119990 A1  | 08/29/2002                     | Madden, et al.                                     |   |
|                       | BM                    | US-US2003/0082228 A1  | 05/01/2003                     | Flowers, et al.                                    |   |
|                       | BN                    | US-   |                                |  |   |

| FOREIGN PATENT DOCUMENTS |                       |                           |                     |                                   |                                |  |   |                          |
|--------------------------|-----------------------|---------------------------|---------------------|-----------------------------------|--------------------------------|--|---|--------------------------|
| Examiner Initials*       | Cite No. <sup>1</sup> | Foreign Patent Document   |                     |                                   | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines,<br>Where Relevant Passages<br>or Relevant Figures Appear | T <sup>6</sup>           |
|                          |                       | Country Code <sup>3</sup> | Number <sup>4</sup> | Kind Code <sup>5</sup> (if known) |                                |  |   |                          |
| AW<br>↓                  | BO                    | PCT                       | WO94/04196          | A1                                | 03/03/1994                     | Imperial Cancer Research<br>Technology Limited     |   | <input type="checkbox"/> |
|                          | BP                    | PCT                       | WO93/25673          | A1                                | 12/23/1993                     | The Regents of the University<br>of California     |   | <input type="checkbox"/> |
|                          | BQ                    | EP                        | 0819758             | A2                                | 01/21/1998                     | James Archibald Mixson                             |   | <input type="checkbox"/> |
|                          | BR                    |                           |                     |                                   |                                |  |   | <input type="checkbox"/> |
|                          | BS                    |                           |                     |                                   |                                |  |   | <input type="checkbox"/> |

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| NON PATENT LITERATURE DOCUMENTS |                          |   |                          |                    |
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| Examiner<br>Initials *          | Cite<br>No. <sup>1</sup> | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T <sup>2</sup>           |                    |
|                                 | BT                       | VERMA, Inder M., et al. "Gene Therapy - promises, problems and prospects", <i>Nature</i> (1997) 389:239-242   | <input type="checkbox"/> |                    |
|                                 | BU                       | ORKIN, Stuart H., et al. "Report and Recommendation of the Panel to Assess the NIH Investment in Research on Gene Therapy", (1995) 1-41   | <input type="checkbox"/> |                    |
|                                 | BV                       | RAZ, E., et al. "Cationic Lipids Inhibit Intradermal Genetic Vaccination", <i>Vaccines</i> (1994) 94:71-75  | <input type="checkbox"/> |                    |
|                                 | BW                       | GAO, Xiang "Cationic Lipid-Based Gene Delivery: An Update", (undated) pp 99-112   | <input type="checkbox"/> |                    |
|                                 | BX                       | RODMAN, David M., et al. "Delivery of Genes Through the Lung Circulation", (undated) Chapter 9, pp. 181-191   | <input type="checkbox"/> |                    |
|                                 | BY                       | FREIMARK, Bruce D., et al. "Cationic Lipids Enhance Cytokine and Cell Influx Levels in the Lung Following Administration of Plasmid: Cationic Lipid Complexes", <i>J. Immunology</i> (1998) 160:4580-4586   | <input type="checkbox"/> |                    |
|                                 | BZ                       | YAMAMOTO, Toshiko, et al. "Lipofection of Synthetic Oligodeoxyribonucleotide Having a Palindromic Sequence of AACGTT to Murine Splenocytes Enhances Interferon Production and Natural Killer Activity", <i>Microbiol. Immunol.</i> (1994) 38(10):831-836        | <input type="checkbox"/> |                    |
|                                 | CA                       | BALLAS, Zuhair K., et al. "Induction of NK Activity in Murine and Human Cells by CpG Motifs in Oligodeoxynucleotides and Bacterial DNA", <i>Journal of Immunology</i> (1996) 157:1840-1845  | <input type="checkbox"/> |                    |
|                                 | CB                       | KRIEG, Arthur M. "Lymphocyte activation by CpG dinucleotide motifs in prokaryotic DNA", <i>Trends in Microbiology</i> (1996) 4(2):73-77   | <input type="checkbox"/> |                    |
|                                 | CC                       | PISETSKY, David S. "The Immunologic Properties of DNA", <i>The Journal of Immunology</i> (1996) 156:421-423   | <input type="checkbox"/> |                    |
|                                 | CD                       | SATO, Yukio, et al. "Immunostimulatory DNA Sequences Necessary for Effective Intradermal Gene Immunization", <i>Science</i> (1996) 273:352-354  | <input type="checkbox"/> |                    |
|                                 | CE                       | STACEY, Katryn J., et al. "Macrophages Ingest and Are Activated by Bacterial DNA", <i>The Journal of Immunology</i> (1996) 157:2116-2122  | <input type="checkbox"/> |                    |
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| AW                              | CF                    | SUN, Siquan, et al. "Dual Function of Drosophila Cells as APCs for Native CD8 <sup>+</sup> TCells: Implications for Tumor Immunotherapy", <i>Immunity</i> (1996) 4:555-564  | <input type="checkbox"/> |  |
|                                 | CG                    | LIU, Yong, et al. "Factors influencing the efficiency of cationic liposome-mediated intravenous gene delivery", <i>Nature Biotechnology</i> (1997) 15:167-173   | <input type="checkbox"/> |  |
|                                 | CH                    | LEITNER, Wolfgang W., et al. "DNA and RNA-based vaccines: principles, progress and prospects" <i>Vaccine</i> (2000) 18:765-777  | <input type="checkbox"/> |  |
|                                 | CI                    | LESOON-WOOD, Leslie A., et al. "Systemic Gene Therapy with p53 Reduces Growth and Metastases of a Malignant Human Breast Cancer in Nude Mice", <i>Human Gene Therapy</i> (1995) 6:395-405   | <input type="checkbox"/> |  |
|                                 | CJ                    | OKAMOTO, T., et al. <i>Proceedings of the American Association for Cancer Research</i> (1997) 38: Abstract #78  | <input type="checkbox"/> |  |
|                                 | CK                    | LI, Xiu-Min, et al. "Mucosal IFN- $\lambda$ Gene Transfer Inhibits Pulmonary Allergic Responses in Mice", <i>The Journal of Immunology</i> (1996) 157:3216-3219   | <input type="checkbox"/> |  |
|                                 | CL                    | McLEAN, John W., et al. "Organ-specific endothelial cell uptake of cationic liposome-DNA complexes in mice", <i>American Journal of Physiology</i> (1997) 273:H3878-H404  | <input type="checkbox"/> |  |
|                                 | CM                    | PISETSKY, David S. "Immune Activation by Bacterial DNA: A New Genetic Code", <i>Immunity</i> (1996) 5:303-310   | <input type="checkbox"/> |  |
|                                 | CN                    | ROMAN, Mark, et al. "Immunostimulatory DNA sequences function as T helper -1- promoting adjuvants", <i>Nature Medicine</i> (1997) 3(8):849-854  | <input type="checkbox"/> |  |
|                                 | CO                    | ROSENBERG, Steven A., et al. "Regression of Established Pulmonary Metastases and Subcutaneous Tumor Mediated by the Systemic Administration of High-dose Recombinant Interleukin 2", <i>J. Exp. Med.</i> (1985) 161:1169-1188                                   | <input type="checkbox"/> |  |
|                                 | CP                    | SCHEULE, Ronald K., et al. "Basis of Pulmonary Toxicity Associated with Cationic Lipid-Mediated Gene Transfer to the Mammalian Lung", <i>Human Gene Therapy</i> (1997) 8:689-707  | <input type="checkbox"/> |  |
| ↓                               | CQ                    | TEMPLETON, Nancy S., et al. "Improved DNA: liposome complexes for increased systemic delivery and gene expression", <i>Nature Biotechnology</i> (1997) 15:647-652   | <input type="checkbox"/> |  |

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| AW                              | CR                    | GREGORIADIS, Gregory, et al. "Liposome-mediated DNA vaccination", <i>FEBS Letters</i> (1997) 402:107-110  | <input type="checkbox"/> |  |
|                                 | CS                    | NAITOH, J., et al. <i>Proceedings of the American Association for Cancer Research</i> (1998) 39: Abstract #2421   | <input type="checkbox"/> |  |
|                                 | CT                    | HO, Rodney J.Y., et al. "Interactions of Target-sensitive Immunoliposomes with Herpes Simplex Virus", <i>Journal of Biological Chemistry</i> (1987) 262(29):13979-13984   | <input type="checkbox"/> |  |
|                                 | CU                    | HO, Rodney J.Y., et al. "Target-sensitive Immunoliposomes as an Efficient Drug Carrier for Antiviral Activity", <i>Journal of Biological Chemistry</i> (1987) 262(29):13973-13978   | <input type="checkbox"/> |  |
|                                 | CV                    | HO, Rodney J.Y., et al. "Target-sensitive Immunoliposomes: Preparation and Characterization", <i>Biochemistry</i> (1986) 25:5500-5506   | <input type="checkbox"/> |  |
|                                 | CW                    | ALLEN, T.M., et al. "Large unilamellar liposomes with low uptake into the reticuloendothelial system", <i>FEBS Letters</i> (1987) 223(1):42-46  | <input type="checkbox"/> |  |
|                                 | CX                    | KLIBANOV, Alexander L. "Amphipathic polyethyleneglycols effectively prolong the circulation time of liposomes", <i>FEBS Letters</i> (1990) 268(1):235-237   | <input type="checkbox"/> |  |
|                                 | CY                    | WOODLE, Martin C., et al. "Sterically stabilized liposomes", <i>Biochimica et Biophysica Acta</i> (1992) 1113:171-199   | <input type="checkbox"/> |  |
|                                 | CZ                    | CORNELIE, S., et al. "Methylated cpG-Containing Plasmid Activates the Immune System", <i>Scandinavian Journal of Immunology</i> (2004) 59:143-151   | <input type="checkbox"/> |  |
|                                 | DA                    | SASAKI, Shin, et al. "Adjuvant formulations and delivery systems for DNA vaccines", <i>Methods</i> (2003) 31:243-254  | <input type="checkbox"/> |  |
|                                 | DB                    | C.J. WHEELER, et al. "A novel cationic lipid greatly enhances plasmid DNA delivery and expression in mouse lung", <i>Proc. Natl. Acad. Sci. USA</i> (1996) 93:11454-11459   | <input type="checkbox"/> |  |
|                                 | DC                    | LIU, Y, et al. "Cationic Liposome-mediated intravenous Gene Delivery", <i>J. Biol. Chem.</i> (1995) 270(42):24864-24870   | <input type="checkbox"/> |  |

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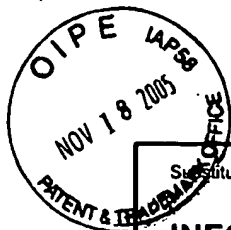
|  |   |    |   |                          |                           |
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|                                 | DD                       | ZOU, Yiyu, et al. "Effective Treatment of Early Endobronchial Cancer With Regional Administration of Liposome-p53 Complexes", <i>J. Natl. Cancer. Inst.</i> (1998) 90(15):1130-1137   | <input type="checkbox"/> |
|                                 | DE                       | OUDRHIRI, Noufissa, et al. "Gene transfer by guanidinium-cholesterol cationic lipids into airway epithelial cells <i>in vitro</i> and <i>in vivo</i> ", <i>Proc. Natl. Acad. Sci. USA</i> (1997) 94:1651-1656   | <input type="checkbox"/> |
|                                 | DF                       | STRIBLING, Roscoe, et al. "Aerosol gene delivery <i>in vivo</i> ", <i>Proc. natl. Acad. Sci. USA</i> (1992) 89:11277-11281  | <input type="checkbox"/> |
|                                 | DG                       | NABEL, Gary J., et al. "Direct gene transfer with DNA-liposome complexes in melanoma: Expression, biologic activity, and lack of toxicity in humans", <i>Proc. Natl. Acad. Sci. USA</i> (1993) 90:11370-11311   | <input type="checkbox"/> |
|                                 | DH                       | LI, Daqing, et al. "Combination Surgery and Nonviral Interleukin 2 Gene Therapy for Head and Neck Cancer", <i>Clinical Cancer Research</i> (1999) 5:1551-1556   | <input type="checkbox"/> |
|                                 | DI                       | PHILIP, Ramila, et al. "In Vivo Gene Delivery", <i>J. Biol. Chem.</i> (1993) 268(22):16087-16090  | <input type="checkbox"/> |
|                                 | DJ                       | HIROAKI, Hemmi, et al. <i>Nature Immunology</i> (2002) 3(2): 196-200  | <input type="checkbox"/> |
|                                 | DK                       |   | <input type="checkbox"/> |

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.



PTO/SB/08A (08-03)

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|---|---|----|--------------------------|------------------------|-----------------|
| Substitute for form 1449A/PTO   |   |    | <b>Complete if Known</b> |                        |                 |
| <b>INFORMATION DISCLOSURE<br/>STATEMENT BY APPLICANT</b><br><br>(use as many sheets as necessary) |   |    | Application Number       | 10/780,114             |                 |
|   |   |    | Filing Date              | February 17, 2004      |                 |
|   |   |    | First Named Inventor     | Dow, Steven W.         |                 |
|   |   |    | Art Unit                 | 1653                   |                 |
|   |   |    | Examiner Name            | A. Wehbe               |                 |
| Sheet   | 1 | of | 1                        | Attorney Docket Number | 021819-000130US |

| U.S. PATENT DOCUMENTS+ |                          |  |                                |  |   |
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| Examiner<br>Initials*  | Cite<br>No. <sup>1</sup> | Document Number                          | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited Document | Pages, Columns, Lines, Where<br>Relevant Passages or Relevant<br>Figures Appear |
|                        |                          | Number Kind Code <sup>2</sup> (if known) |                                |  |   |
| AW                     | AA                       | US-2003/0022854 A1                       | 01/30/2003                     | Dow, et al.  |   |
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|                        | AG                       | US-                                      |                                |  |   |
|                        | AH                       | US-                                      |                                |  |   |
|                        | AI                       | US-                                      |                                |  |   |
|                        | AJ                       | US-                                      |                                |  |   |
|                        | AK                       | US-                                      |                                |  |   |
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| Examiner<br>Initials*    | Cite<br>No. <sup>1</sup> | Foreign Patent Document   |                     |                                   | Publication Date<br>MM-DD-YYYY | Name of Patentee or<br>Applicant of Cited<br>Document | Pages, Columns, Lines,<br>Where Relevant<br>Passages or Relevant<br>Figures Appear | T <sup>6</sup>           |
|                          |                          | Country Code <sup>3</sup> | Number <sup>4</sup> | Kind Code <sup>5</sup> (if known) |                                |   |  |                          |
| AW                       | AU                       | PCT                       | WO99/66879          | A2                                | 12/29/1999                     | National Jewish Medical<br>and Research Center        |  | <input type="checkbox"/> |
|                          | AV                       |                           |                     |                                   |                                |   |  | <input type="checkbox"/> |
|                          | AW                       |                           |                     |                                   |                                |   |  | <input type="checkbox"/> |
|                          | AX                       |                           |                     |                                   |                                |   |  | <input type="checkbox"/> |
|                          | AY                       |                           |                     |                                   |                                |   |  | <input type="checkbox"/> |
|                          | AZ                       |                           |                     |                                   |                                |   |  | <input type="checkbox"/> |
|                          | BA                       |                           |                     |                                   |                                |   |  | <input type="checkbox"/> |
|                          | BB                       |                           |                     |                                   |                                |   |  | <input type="checkbox"/> |

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|-----------------------|---------------------------------|--------------------|------------|
| Examiner<br>Signature | /Anne Marie Wehbe/ (01/31/2007) | Date<br>Considered | 01/31/2007 |
|-----------------------|---------------------------------|--------------------|------------|

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